DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

MJ937n

September 2, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-

William A. Soderlund
Pharmacist-In-Charge
Veterinary Pharmacy Corporation
201 South 3rd Street
St. Peter, MN 56082

Dear Mr. Soderlund:

An inspection of your pharmacy located in St. Peter, Minnesota on May 17, 18, 25-27, 1999 by our investigator found that you are compounding veterinary drugs for use in food producing animals, mainly swine, in violation of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). The compounded animal drugs, including sulfadiazine/trimethoprim, lincomycin injectable, tylosin/dexamethasone/ampicillin, are unapproved new animal drugs.

Under the Act, Section 201(g), a drug is an article which is intended to prevent or treat a disease or other condition; or which is intended to affect the structure or function of the body. A new animal drug, Section 201(v), is an animal drug which is not generally recognized as safe and effective by qualified experts. To be found safe and effective by experts (and not require FDA approval) there must be adequate and well controlled safety and effectiveness studies for the specific product, not a similar product, in the open scientific literature which the experts can review. These studies do not exist for any of your compounded products. A new animal drug application, which establishes that they are safe and effective, must be submitted and approved for these, and any other food animal products you make before they can be legally marketed.

The courts have held that the animal drug approval requirements of the Act apply to animal drugs compounded from unapproved bulk drugs, see United States v. 9/1kg. Containers, More or Less of an Article of Drug for Veterinary Use (7th Cir. 1988) and United States v. Algon Chemical Inc., a corporation (3rd Cir. 1989). This was reaffirmed with the recent passage of the Animal Medicinal Drug Use Clarification Act (AMDUCA) and regulation 21 CFR 530.13(a) which explicitly states "nothing in this part shall be construed as permitting compounding from bulk drugs." AMDUCA allows compounding from approved human and animal drugs when the conditions established by the regulations have been met, not bulk unapproved products.

The above is not intended to be an all-inclusive list of violations. As a pharmacy, you are responsible for assuring that your overall operation and the products you compound and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

Edwin S. Dee
Acting District Director
Minneapolis District

xc: Patrick L. Soderlund
Veterinary Pharmacy Corporation
201 South 3rd Street
St. Peter, MN 56082